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EXAMINER

FOX, D

18M2/0131

ART UNIT

PAPER NUMBER

JOSEPH T EISELE
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1803
DATE MAILED:

01/31/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS This application has been examined Responsive to communication filed on 1/1/95 This action is made final.A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION1. Claims 2-4, 7-8, 13-16, 20-30 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. Claims 1, 9-12, 17-19 have been cancelled.3. Claims 20 are allowed.4. Claims 2-4, 7-8, 13-16, 21-30 are rejected.5. Claims _____ are objected to.6. Claims _____ are subject to restriction or election requirement.7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.8. Formal drawings are required in response to this Office action.9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. 07/629,216; filed on 12/17/90.13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.14. Other**Best Available Copy****EXAMINER'S ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-4, 7-8, 13-16, 22 and 24-26 (amended), and claims 29-30 (newly submitted) are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,387,756. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the transgenic plant transformed with a plasmid comprising the starch metabolism phosphofructokinase gene claimed in the patent to obtain the transgenic plants comprising starch metabolism genes including the phosphofructokinase gene as newly claimed in the instant application, as stated in the last office action for claims 1, 10-12 and 17-18. The indication in the last office action that the claim of the patent was drawn to the ADPGPPP gene was an inadvertent error, as evidenced by the lack of inclusion of claim 20, drawn to the ADPGPPP gene, in the double patenting rejection in the last office action.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The double patenting rejection will be maintained until receipt of a properly executed Terminal Disclaimer.

Claim 23 (newly amended) is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 is indefinite in its dependence upon cancelled claim 9.

Claims 2-4, 7-8, 13-16 and 21-26 (amended), and claims 27-30 (newly submitted) are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to transgenic plants comprising either an introduced phosphofructokinase gene or an ADPGPP gene, as stated in the last office action for claims 1-4, 7-19 and 21-26. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claim 30 (newly submitted) is rejected under 35 U.S.C. § 102(b) as being anticipated by Grill et al., as stated in the last office action for claims 1, 7, 10-12 and 17-18.

Claim 30 (newly submitted) is rejected under 35 U.S.C. § 103 as being unpatentable over Houck et al. taken with Gay et al., as stated in the last office action for claims 1 and 17.

Claims 2-4, 7-8, 13-16, 21-24 and 30 (newly submitted) are rejected under 35 U.S.C. § 103 as being unpatentable over Twell et al. taken with de Graaff et al., Ap-Rees et al. and Yang et al., as stated in the last office action for claims 1-4, 7-19 and 21-24.

Claims 20, 25-26 and 27-29 (newly submitted) are deemed free of the prior art, for the reasons stated in the last office action for claims 20 and 25-26.

Claim 20 is allowed.

Applicants' arguments filed 1 November 1995 have been fully considered but they are not deemed to be persuasive.

Applicants urge that rejection of the claims under 35 USC 112, first paragraph, is improper, given the previous isolation of the claimed genes, the demonstration by another worker of the claimed effects following transformation with the acid invertase gene, the ability of the skilled artisan to select transformed plants which did not exhibit deleterious effects, Applicants' transformation with an antisense acid invertase construct and a sucrose synthase construct, and the alleged inapplicability of the Ap-Rees et al. reference cited by the Examiner.

The Examiner maintains that von Schaewen et al. demonstrate deleterious effects on plant health following transformation with the acid invertase gene, as well as variability both within and between plant species, thus demonstrating the unpredictability inherent in the process. Applicants' specification does not

provide any guidance regarding the transformation or evaluation of plants with non-exemplified genes. Furthermore, the claims are broadly drawn to any plant species, at least eight genes, and in one instance any gene (claim 30).

See Ex parte Forman, 230 USPQ 546, 547 (PTO Bd. App. Int. 1986), where it was taught that "the disclosure of a patent application must enable practice of the invention claimed without undue experimentation", wherein factors involved in the determination of undue experimentation were deemed to include "the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims." See also Ex parte Hitzeman, 9 USPQ 2d 1821, 1823 (PTO Bd. App. Int. 1988), where the unpredictable physiological art was deemed to require more than one embodiment for the enablement of broad claims.

Applicants' assertions that the skilled artisan could select unaffected plants are not deemed persuasive, particularly as it is unclear whether the unaffected plants possessed the introduced gene, exhibited expression of the gene, or would exhibit changes in sugar and starch content.

Applicants' results following transformation with antisense invertase or sucrose synthase constructs are not deemed

probative, as they are not in declaration form. Furthermore, the claims are not drawn to antisense constructs, so that the applicability of this data is unclear. In addition, the results involve potato, while the claims are broadly drawn to any plant.

Regarding the Ap-Rees et al. reference, claim 19 has been canceled, so that Applicants' arguments regarding this reference are deemed moot.

Applicants urge that rejection of the claims under 35 USC 102 is improper, given the failure of the cited prior art to teach the genes claimed in claim 2, upon which claim 7 depends. The Examiner maintains that newly submitted claim 30 does not specify a particular gene, similar to newly cancelled claims 1, 10-12 and 17-18 previously included in the rejection.

Applicants urge that rejection of the claims under 35 USC 103 is improper, given the failure of the cited references to teach the allegedly unexpected results of the instant invention, i.e. the regulation of glycolytic flux at the exit of carbon from the pathway, and the concomitant change in sugar and starch content.

The Examiner maintains that the combination of references does suggest the claimed invention, particularly given the suggestion to transform potato by Twell et al. and Yang et al. and the teaching by Ap-Rees et al. of the involvement of enzymes such as pyruvate kinase in the accumulation of sugars in potatoes. It is noted that only a reasonable expectation of

success is required for determinations of obviousness, as taught in In re O'Farrell, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

Furthermore, the claims are broadly drawn to any gene and any plant, while Applicants' evidence is limited to each of two genes, and in many instances a single plant species. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims. Finally, it is noted that Applicants have not provided any evidence regarding the effects of the pyruvate kinase gene.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under

37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of \$750 for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Robinson, can be reached on Monday through Friday at (703) 308-2897.

The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 24, 1996

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

David T. Fox